

National Cancer Institute
Institutional Review Board

AGENDA

May 18, 2015

1:00 – 5:00 pm

10 CRC/3-1608

- 1. Review of Draft Minutes, May 4, 2015**
- 2. Announcements**
- 3. Old Business**
- 4. New Business** Model Consent: Genomic Sequencing (Kathy Calzone)
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Response to Stips** P141726, "Phase I/II Study of the Anti-programmed Death Ligand-1 Antibody (a PD-L1 inhibitor) MEDI4736 in Combination with Olaparib or Cediranib for Advanced Solid Tumors and Recurrent Ovarian Cancer" - Jung-Min Lee, PI
- 9. Amendment** 03C0277-X, "Cell Harvest and Preparation for Surgery Branch Adoptive Cell Therapy Protocols" - Steve Rosenberg, PI
- 10. Amendment** 13C0153-E, "A Phase II Trial of Enzalutamide in Combination with PSA-TRICOM in Patients with Non-metastatic Castration Sensitive Prostate Cancer" - Ravi Madan, PI
- 11. Amendment** 13C0146-H, "A Randomized Phase II Trial Combining Vaccine Therapy with PROSTVAC/TRICOM and Enzalutamide vs. Enzalutamide Alone in Men with Metastatic Castration Resistant Prostate Cancer" - Ravi Madan, PI
- 12. Amendment** 14C0037-C, "A Phase 2 Study of the MET Kinase Inhibitor INC280 in Papillary Renal Cell Cancer" - Ramaprasad Srinivasan, PI
- 13. Amendment** 12C0170-I, "A Phase 1B Study to Evaluate the Safety and Induction of Immune Response of CRS 207 in Combination with Pemetrexed and Cisplatin as Front-line Therapy in Adults with Malignant Pleural Mesothelioma" - Raffit Hassan, PI
- 14. Amendment** 11C0113-J, "A Pilot Study of Genetically Engineered NY-ESO-1 Specific (c259) T cells in HLA-A2+ Patients with Synovial Sarcoma" - Crystal Mackall, PI
- 15. Initial Review** P152194, "A Phase 1b/2 Study of AZD9668, an Oral Neutrophil Elastase Inhibitor, in Bronchiolitis Obliterans Syndrome After Allogeneic Hematopoietic Stem Cell Transplantation" - Steven Pavletic, PI
- 16. Initial Review** P152199, "A Phase 2, Open-label, Single-arm, Intra-subject Dose-escalation Study to Investigate the Biological Activity, Safety, Tolerability, and Pharmacokinetics of Ponesimod in Subjects with Symptomatic Moderate or Severe Chronic GVHD Inadequately Responding to First or Second Line Therapy" - Steven Pavletic, PI